Bandolier 69

What do we think?
What do we know?
What can we prove?

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I WANT IT NOW!

Not just the words of a child in one of its phases, but actually a much more pervasive sentiment. New interventions, including pharmaceutical interventions, are often judged on the basis of trials with relatively small numbers of patients. The average is said to be about 1,500, though there is a trend for much larger trials.

Of course the regulatory bodies see all the information they need, but the poor bloody infantry have to make do with "data on file", or abstracts, or "the paper will be available shortly in X, Y or Z journal". But the poor bloody infantry have learned to be more sceptical, and want to see the information for themselves, let alone at health authority or primary care group level.

Relenza landmark

Relenza is a landmark, not because it is the first NICE report, but because the information on which the evaluation was based is up there on the web for all to see. We review it in this issue of ***Bandolier***. Why can't we have something similar at every new drug launch?

Useful answers

It is said that when the USA went into space, they found that ballpoint pens didn't work, so spent £25 million inventing one that did. You can buy a zero-g pen for Christmas! The Russians just used a pencil.

Reviewers should remember that those of us who use reviews want a simple answer fast. We are the Russians, who don't have the super-pens, just a pencil and the back of an envelope. So use statistical outputs by all means, but just tell us the answer in simple, plain English!

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INGROWING TOENAIL TREATMENTS

Why are ingrowing toenails a source of humour? As one ***Bandolier*** confidant said - "they hurt". Ingrowing toenails predominantly affect the big toe, often in adolescents and young adults because they have sweaty feet which softens the skin and nails. About 10,000 new cases needing treatment are thought to occur in the UK every year, about 20 per primary care group of 100,000 people.

Advice about basic foot care and appropriate footwear is sometimes enough to relieve the symptoms of pain and discomfort. Sometimes, though, it is necessary to remove the spike of nail growing into the skin causing the discomfort, with attempts to destroy the nail matrix to prevent regrowth. A systematic review [1] has examined the efficacy of various treatments.

Studies

A typically thorough Cochrane search eventually yielded nine randomised studies examining different methods of surgical nail treatments. The primary outcome was nail regrowth, and studies had to have a minimum follow up period of six month to allow for this to be measured adequately. One Dutch study was not included, awaiting translation, and information is being sought from authors to try and include information from other studies.

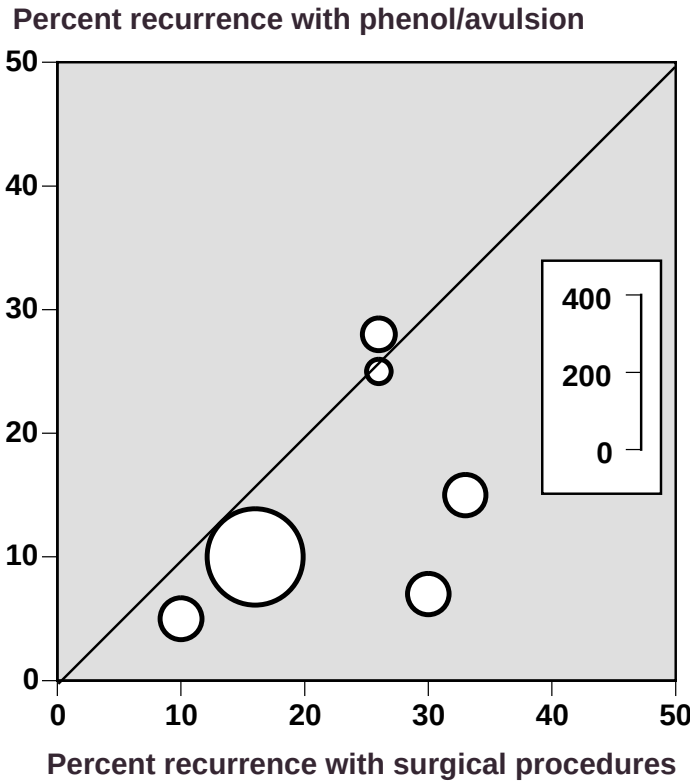
Results

Comparisons were predominantly between avulsion of the nail with phenol treatment of the nail bed to prevent regrowth and several simple surgical procedures. For simplicity, and because there appeared to be no difference between the different procedures, these surgeries were combined.

Symptomatic recurrence at six months or more occurred in 14/288 (5%) patients treated with avulsion/phenol, and 33/297 (11%) patients treated surgically. For every 16 patients treated using avulsion/phenol, one would not have a symptomatic recurrence who would have had if they had been treated surgically (95% confidence interval 9 to 53).

Any recurrence (symptomatic or otherwise) at six months or more occurred in 46/352 (13%) patients treated with avulsion/phenol, and 82/367 (22%) patients treated surgically (Figure). For every 11 patients treated using avulsion/phenol, one would not have a recurrence, symptomatic or not, who would have had if they had been treated surgically

Figure: Individual trials showing the percentage recurrence (symptomatic or asymptomatic) of ingrowing toenails with surgery and phenol/avulsion. Diameter of point is proportional to number of patients in trial



(95% confidence interval 7 to 27). A brief examination of the non-included Dutch paper with 200 comparisons shows that even if included it would have made only minor changes for this outcome.

Postoperative infection was reported in only two trials with 147 patients. It occurred in 12% of patients treated with avulsion/phenol and 18% of those treated surgically. This was not significantly different.

Comment

It is being suggested that ingrowing toenails are increasing in incidence in people treated for fungal nail infections, with 19 of 100 needing surgery [2]. The message is that both avulsion with phenol and surgical excision of ingrowing toenails work. Nine out of 10 patients will have no symptomatic recurrence over six months or more.

Combining the data from all the trials suggests that avulsion with phenol is statistically better than surgical excision, but one can see plenty of room for moving goalposts. The difference between the two techniques is small, and appropriateness will depend on local circumstances.

Reference:
1 C Rounding, S Hulm. Surgical treatments for ingrowing toenails. Cochrane Library 1999 issue 3 (13 March 1999).
2 KL Connelley, SM Dinehart, R McDonald. Onychocryptosis associated with the treatment of onychomycosis. J Am Podiatr Med Assoc 1999 89: 424-6.

Evidence on Zanamivir (Relenza)

The National Institute of Clinical Excellence (NICE) has issued guidance to the NHS concerning the use of zanamivir in the treatment of influenza. It has also posted on its Internet site (www.nice.org.uk) a summary of the evidence used in making its decision (www.nice.org.k/appraisals/sum_evid.htm).

Search

NICE conducted a widespread search, and examined studies that were randomised, compared zanamivir with placebo or current therapy in adults with influenza A or B infections. Excluded were studies addressing prophylaxis, which did not use the licensed dosing and formulation or which looked at experimentally induced influenza.

This left three studies, one of which was published in full [1]. These three studies had 813 patients given zanamivir and 775 given placebo. The high risk population (patients with chronic respiratory, cardiovascular or metabolic disorders, or who were immunocompromised or older than 65 years) numbered 217 patients. Another study [2] was not included, though the reason for its exclusion is unclear (at time of writing).

Outcomes

The primary outcome was time for symptoms to be alleviated. A secondary outcome was the number of patients with complications, most commonly pulmonary disorders including bronchitis, pneumonia and chest infections, though these are not described in any detail.

Results

Overall, about 73% of patients had influenza infection confirmed by laboratory tests. The median reduction in the number of days of illness was one day (Table 1) for all patients. It was 1.5 days (95% CI 1 to 2 days) in patients with confirmed influenza infection and 2.5 days in the high risk group, though this was not statistically better than placebo. A similar reduction was seen in the additional trial [2] not considered by NICE (Table 1).

Rates of complications of influenza infection were lower with zanamivir than with placebo (Table 2), for all patients (intention to treat analysis) and for those with influenza infection and the high risk group. The reduction in high risk patients was not significantly different from placebo. The number of patients needed to be treated to prevent one complication of influenza infection was 14 (95% CI 9 to 33).

Comment

Access to the information upon which NICE based its judgements is terrific, and the NICE Internet site is one to be bookmarked for the future. Having a brief (only five printed pages without references) outline of the current evidence on a new product is just what the doctor ordered. It is what

Table 1: Intention to treat analysis showing primary outcome of median days of illness with influenza with placebo and zanamivir, for three phase III studies examined by NICE, plus one additional study.

Trial	Number of patients	Median illness days		Reduction in illness days (95%CI)
		Placebo	Zanamivir	
3001	455	6.5	5.0	1.5 (0.5 to 2.3)
3002	777	6.0	5.5	0.5 (-0.5 to 1.0)
3003	356	7.5	5.0	2.5 (0.8 to 3.5)
Overall	1588	6.0	5.0	1 .0 (0.5 to 1.5)
Hayden et al, 1997	276	6.0	5.3	0.7 (0 to 1.4)

Intention to treat analysis

we want for every new product, especially when so much material we need is in press, and we have to feed off scraps of conference abstracts and data on file. The need for a systematic review is at launch, not years later. There is clearly a tension between companies which want information available early, and journals, which want the exclusivity of the original papers. But that's not our problem. If we all said that we want a systematic review at launch, and we want it NOW, then ***Bandolier*** guesses it might somehow be done.

It is hard, on the evidence presented, to argue with NICE's conclusions on Relenza. For a fast track appraisal done in a very short time, this is good stuff and NICE should be congratulated. Is there anything missing? There is an outline of the health economic arguments given, but not in enough depth to get to grips with. The most cogent health economic argument probably lies in reduction of complications of influenza in patients at high risk, but the small numbers and lack of statistical benefit makes this an impossible line of argument to follow. Some modelling to give us an idea of how much benefit would be needed to make a clinical and cost difference is an obvious next step for someone.

It is sad, perhaps, that this first NICE appraisal is negative about a product. Conflict between the NHS and healthcare industries is in the best interests of neither. There are lessons to be learned here, about outcomes for patients, professionals and the NHS and industry, and about the general benefits of cooperation.

References:

1 MIST study group. Randomised trial of efficacy and safety of inhaled zanamivir in treatment of influenza A and B virus infections. Lancet 1998 352: 1877-81.

2 FG Hayden et al. Efficacy and safety of the neuraminidase inhibitor zanamivir in the treatment of influenzavirus infections. New England Journal of Medicine 1997 337: 874-80.

Table 2: Intention to treat analysis showing secondary outcome of complications of illness with influenza (mainly pulmonary disorders like bronchitis, pneumonia and chest infections) with placebo and zanamivir, for three phase III studies examined by NICE.

Analysis	Complications with		Relative benefit (95%CI)	NNT (95%CI)
	Placebo (%)	Zanamivir (%)		
Intention to treat	211/775 (27%)	163/813 (20%)	0.74 (0.62 to 0.89)	14 (9 to 33)
Influenza positive	152/558 (27%)	119/609 20%)	0.73 (0.59 to 0.90)	13 (8 to 35)
High risk	46/117 (39%)	26/99 (26%)	0.68 (0.46 to 1.02)	8 (4 to 150)

DID NOT ATTEND

These are fateful words for many different healthcare clinics. A patient who fails to attend means that resources allocated to that patient are not used. High rates of nonattendance produce inefficiencies and waste. Three questions arise from this - what sort of rates of nonattendance occur, why do they occur, and is there anything that can be done to reduce nonattendance?

Bandolier sought to find evidence to answer these questions. This was done by referring to a systematic review current up to 1990 [1], and by a search of PubMed for articles on nonattendance looking for surveys and trials performed since about 1990. The main findings from the ***Bandolier*** search are shown in the Table, but the search was probably not exhaustive.

What are rates of nonattendance?

The review quoted nonattendance rates of 19% to 52%, and found an average nonattendance rate of 43% with a range of 6% to 92%. The more recent information in the Table shows nonattendance rates of between 5% and 38% in UK studies, with 21% nonattenders at clinics in Dunedin, and somewhat higher rates in the USA.

Why do patients not attend?

The studies that have asked this question consistently come up with two major reasons. The first is that patients forgot. The other reason is that clerical errors or communication failures meant that patients did not know they had an appointment.

Can nonattendance rates be reduced?

The systematic review [1] examined randomised trials with quantitative data on the effect of interventions to improve attendance at healthcare appointments. They found 23 trials up to 1990, and the interventions were, in the main, simple telephone or written reminders. For letter and telephone prompts, the reported outputs were as odds ratios, with odds ratios of between 2 and 3.

Three additional randomised trials and one controlled trial of telephone or written prompts were found since the original review (Table, with randomised or controlled trials in grey). They all reduced nonattendance rates and also produced odds ratios of about 2 or 3. Giving patients referred to hospital a copy of the referral letter did not reduce nonattendance rates, though the rate of nonattendance, at 5%, was so low that there was little room for much benefit to be demonstrated.

Odds ratios are not very helpful, and the percentage of nonattenders varies considerably. So the review helpfully generates the number of patients who have to be sent a reminder for one additional patient to attend for their appointment (Figure).

- When nonattendance rates are below 10%, 25 have to be sent a reminder for one additional attendance.
- When nonattendance rates are about 20%, 10 have to be sent a reminder for one additional attendance.
- When nonattendance rates are about 35%, 6 have to be sent a reminder for one additional attendance.
- When nonattendance rates are above 50%, 5 have to be sent a reminder for one additional attendance.

Comment

Bandolier has not done a complete review with full meta-analysis and economic assessment here, partly because of time and partly because it isn't needed. We know that nonattendance rates are variable, if often too high. We know that simple interventions are effective, and similarly effective, across a range of nonattendance rates. We know that every clinic has its own idiosyncrasies which makes a nonsense of generalities about economic assessment. A problem may be that all the randomised trials are American, and have high nonattendance rates. This may make generalisation problematical.

The one generality that is of use is the NNT calculation. Any clinic could audit its nonattendance rate and judge the cost and consequences of instituting simple postal or telephone reminders.

Reference:
1 WM Macharia et al. An overview of interventions to improve compliance with appointment keeping for medical services. JAMA 1992 267: 1813-1817.

Figure: NNTs for simple telephone or postal reminders depending on the percentage of nonattenders.

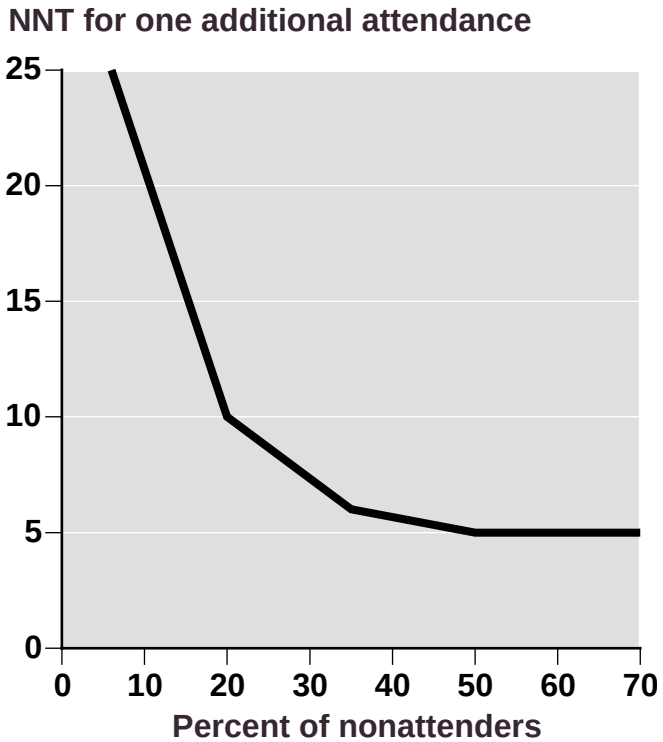


Table: Results of *Bandolier* search for articles related to patient nonattendance at clinics. Studies in grey are controlled trials

Reference	Place	Setting	Number	Result
McGlade et al, BMJ 1988 297:1246-8	Belfast	First hospital appointment made by GP	269 referrals	15% of all patients failed to attend
Kane, Radiogr Today 1991 57:15-9	Manchester	One year audit of outpatient X-ray department	5,323 appointments	5% of all patients failed to attend. Main reason in 51 non-attenders was illness
Lloyd et al, Fam Pract 1993 10:111-7	London	ENT and gastroenterology outpatient clinics	1492 first time appointments	26% failed to attend ENT 20% failed to attend gastroenterology
Verbov, JR Soc Med 1992 85:277-8	Liverpool	Dermatology outpatients	100 non attenders	28% DNA because of illness, and 33% DNA because of problems related to the appointment
Dockerty, NZMed J 1992 105:147-9	Dunedin, NZ	Outpatient appointments at Dunedin hospital over 6 months	37,271 appointments	21% failed to attend
Potamitis et al, JR Soc Med 1994 87:591-3	Birmingham	13 month survey of eye hospital outpatients	5,248 appointments	10% failed to attend. Main reasons were clerical errors and forgetting appointment
Bottomley et al, Clin Exp Dermatol 1994 19:399-400	Leeds	New referrals at dermatology outpatients over 12 months	Number not available	19% failed to attend. Main reason were forgetting appointment and communication failure
Herrick et al, J Dent 1994 22:307-9	Argyll & Clyde	Periodontal clinic	Number not available	Main reasons for non attendance were forgetting appointment and communication failure
Dini et al, Arch Pediatr Adolesc Med 1995 149:902-5	Atlanta, USA	RCT for public health clinic appointments - normal versus computer-generated telephone appointment	517 appointments	68% failed to attend without reminder 48% failed to attend with reminder Statistically significant improvement
King et al, JR Soc Med 1995 88:88-90	Liverpool	Ophthalmic outpatients survey over 1 year	43,004 appointments	13% failed to attend.
Ross et al, Genitourin Med 1995 71:393-5	Edinburgh	Four clinics surveyed over 1 month	Number not available	15% DNA at genitourinary clinic 13% DNA at medical clinic 15% DNA at surgical clinic 14% DNA at dermatology clinic
Komoroski et al, Pediatr Emerg Care 1996 12:87-90	Little Rock, USA	RCT for follow-up appointments after emergency department visit, various reminders	253 patients and families	76% failed to attend without reminder 53% failed to attend with simple written reminder 48% failed to attend with written reminder and other interventions Statistically significant improvement
Simmons et al, JR Coll Physicians Lond 1997 31:70-3	Leeds	General medical and gastroenterology outpatient clinic, new patients	Number not available	38% failed to attend
O'Brien et al, Pediatrics 1998 101:E6	Cleveland, USA	RCT of adolescent routine appointments with telephone reminder	703 appointments	57% failed to attend without reminder 35% failed to attend with reminder Statistically significant improvement
Reekie et al, Br Dent J 1998 185:472-4	Manchester	Trial of postal reminder versus no reminder in single-handed dental practice	1000 attendances	9% failed to attend without reminder 3% failed to attend with reminder
Stone et al, JR Soc Med 1999 92:114-8	Exeter	6 month prospective survey of plastic surgery outpatient clinic	6,095 appointments	16% failed to attend
Hamilton et al, BMJ 1999 318:1392-5	Exeter	RCT of giving referral letter to patients attending outpatients	2,078 referrals	5% failed to attend without copy of letter 5% failed to attend with copy of letter

SEXUAL HEALTH SURVEY

Bandolier 65 featured a survey on sexual health in the USA. Another survey [1] examined sexual problems in the UK.

Survey

Four diverse general practices in England participated, and from each register a random sample of 1000 people was selected of men and women in different age groups between the ages of 18 and 75. A questionnaire was piloted and then sent to people selected from the registers, with a letter from the practice emphasising the importance of the work and the anonymity of the questionnaire. Questionnaires for men and women were different.

Results

The response rate was 39% for men and 49% for women, with 1768 responses in total. One third of responders had not had sex at all during the previous three months, and one fifth reported having sex more than once a week.

The current and lifetime sexual problems reported by women and men are shown in the Table. For women, vaginal dryness and never or rarely experiencing a climax were common. For men common problems were getting and maintaining an erection, and premature ejaculation.

About half the responders said they would like to receive help for sexual problems, but only about 5% of those who wanted help had received it. Given an opportunity to choose whence such help would be most welcome, there was a preference for family doctor, family planning or well (wo)man clinic or trained marriage guidance counsellor.

Table: Common sexual problems in women and men in the UK

	Percent with sexual problem	
Problem	**Current**	**Lifetime**
Women		
Never or rarely climax	27	
Pain during intercourse	18	45
Vaginal dryness	28	49
Problems with arousal	17	
Sex never or rarely pleasant	18	
Any of these	**41**	
Any lifetime problem		**68**
Men		
Difficulty getting erection	21	23
Difficulty maintaining erection	24	25
Either or both of these	26	39
Premature ejaculation	14	31
Sex never or rarely pleasant	9	
Any of these	**34**	
Any lifetime problem		**54**

Comment

These results are strikingly similar to those found in the US survey in ***Bandolier*** 65. It highlights a high prevalence of sexual problems, with a gap between need and provision.

References:
1 KM Dunn, PR Croft, GI Hackett. Sexual problems: a study of the prevalence and need for health care in the general population. Family Practice 1998 15: 519-24.

PREMATURE EJACULATION TREATMENTS

Premature ejaculation or climaxing too early was a problem that occurred with 31% of men in the sexual surveys in this ***Bandolier*** and in ***Bandolier*** 65. Fourteen percent of men reported this to be a current problem. By any definition, this, like other issues from the sexual surveys, was common. So ***Bandolier*** did a quick search to see whether there was a literature on effective treatments.

Premature ejaculation has been defined as persistent or recurrent ejaculation with minimal sexual stimulation before, during, or after intromission and before the patient wishes it. There have been a number of psychological approaches to treatment, though we could not find any papers that defined the effectiveness of these approaches. We may have been looking in the wrong place. But a number of antidepressants have delayed ejaculation as an adverse effect, and these have been tested in randomised trials. ***Bandolier*** thought this merited a quick review.

Search

Several searches were done using MEDLINE, PubMed and the Cochrane Library using the terms premature ejaculation and individual drug names. Twenty-one studies appeared to be randomised, controlled trials of use of antidepressants in men with premature ejaculation. Three of them were not controlled studies, and were excluded. Copies of five studies could not be obtained within two months. Full citations for all of these studies are on the ***Bandolier*** Internet site.

Outcomes

The main outcome in all studies was the intravaginal latency time, usually measured by men at home using a bedside stop-clock. Almost all studies included only men with intravaginal latency times of less than one minute, though a few included men with longer times.

Interventions

Various antidepressants were used, at varying doses. Studies divided between those in which men were instructed to take the drugs some time before expected intercourse (usually four to six hours) and those in which drugs were taken daily.

Results

Full details and references are available from electronic ***Bandolier***. Two studies included men without premature ejaculation as controls, and in these the average intravaginal latency time was eight or nine minutes, and was minimally increased by antidepressants.

Antidepressants were variably effective in men with premature ejaculation. The Figure shows the intravaginal latency times for placebo and antidepressants for drugs taken before sexual activity and with daily dosing. Pooling of data and calculation of NNTs was not possible.

Adverse effects were those associated with antidepressants. Ejaculatory failure was noted occasionally, though this was reversed when drugs were stopped or dose reduced.

Comment

There are a number of points that need to be emphasised.

1. This is a preliminary and quick review of the literature. It is less than a full systematic review.
2. Not all of the published work could be obtained. While it was frustrating that five papers could not be read, their abstracts generally supported the general conclusion that antidepressants were effective. There may be other studies we did not find.
3. We could find no patient-orientated definition of what was a useful increase in intravaginal latency.
4. There was little information on what was a normal intravaginal latency, and though mean times for control subjects in two studies suggested eight or nine minutes, there is clearly great variation, both in individuals and in circumstances.
5. Not all men responded equally. Some men had large increases in intravaginal latency, whilst in others it was minimal [1]. Perhaps about half had increases to over two minutes.
6. Men included generally had intravaginal latency times of less than one minute, and could be defined as having the most severe problem. How antidepressants would affect men with less moderately impaired intravaginal latency was not investigated.

This all being said, many authors comment that the increases in intravaginal latency were clinically significant. Moreover, the treatment appears to be one that is not necessarily for ever. One author [2] reported that in an open continuation after a trial, 67% of patients were able to discontinue treatment after four-weekly trials of staged withdrawals, with a mean latency time of 4.1 minutes.

References:
1 DS Strassberg et al. Clomipramine in the treatment of rapid (premature) ejaculation. Journal of Sex and Marital Therapy 1999 25: 89-101.
2 CG McMahon. Treatment of premature ejaculation with sertraline hydrochloride: a single-blind placebo controlled crossover study. Journal of Urology 1998 159: 1935-1938.

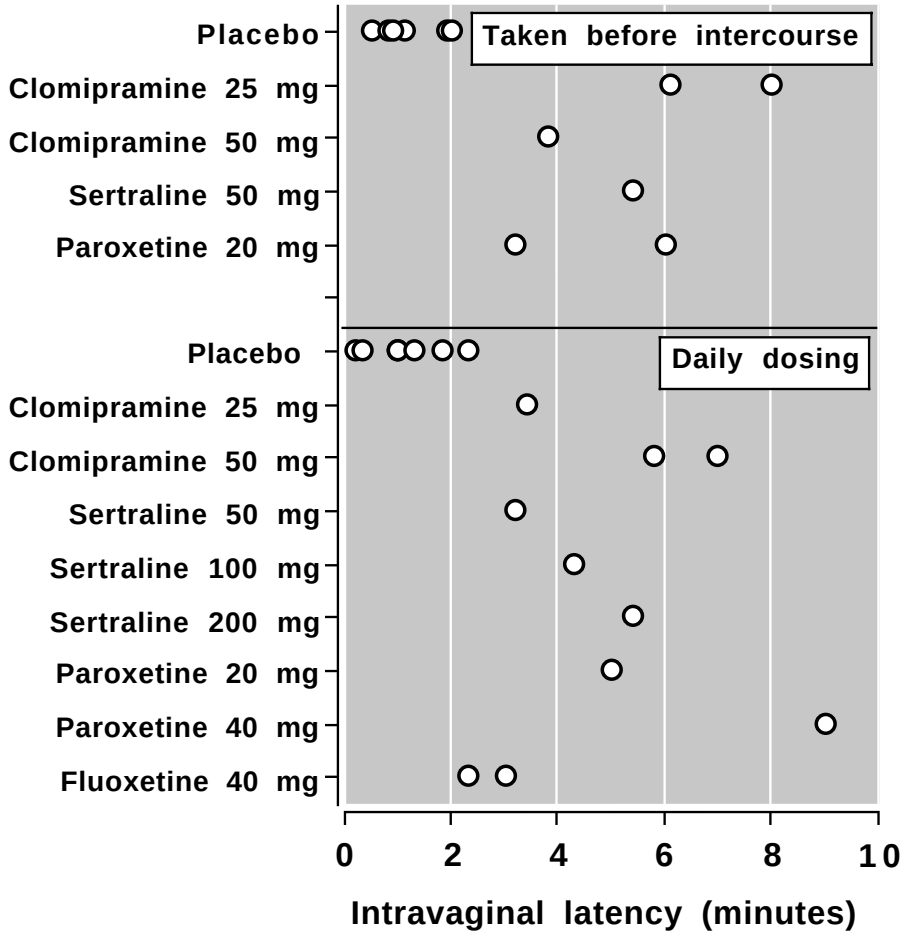


Figure: Each point represents the intravaginal latency time for drug or placebo in a single arm of a randomised trial

Book review

Pain the science of suffering: PD Wall. Weidenfeld and Nicolson 1999 pp178 £14.99, ISBN 0 297 84255 2

Patrick Wall is an intellectual colossus in the pain world, and he has written a lovely book. There is something magical when a wise person looks back over the field which they have studied for many years. This book has that magic, clear writing coupled with insight.

The science is leavened by stories, vignettes about people and their pain. These Professor Wall uses to illustrate the complexity of pain, and to show how daft it is to expect simple solutions when the problem is anything but simple. The science is physiology with some pharmacology, and is written for an intelligent lay reader. It is followed by chapters on pain with obvious cause, and pains without such obvious cause. These are clearly and fairly written. The misery of fibromyalgia, for instance, is not dismissed just because we don't understand the cause.

Chapters about treatments allow Professor Wall to expand his important theme, important for both patients and doctors, that miraculous cures are unlikely to emerge in chronic pain from interventions which cause permanent damage to the nervous system. The inevitable 're-wiring' may result in worse pain, albeit after a pain-free period. Our ignorance about the mechanisms of treatments which do work is well covered, with an open intellectual curiosity. The sections on complementary medicine are entertaining and fair. The concept of hypnosis underlying acupuncture makes you think. Caveat emptor is an appropriate conclusion.

Towards the end of the book comes the suggestion that the brain representation of pain in common with some other sensations may be as the likely motor response. The distinction drawn is between pain as a signal of a painful stimulus, or pain as a signal of "the stage reached in a sequence of possible actions". Here Professor Wall elegantly mops up placebo effects. He argues that if the sensation of pain is associated with a series of potential actions, remove painful stimulus, change posture, seek safety, apply therapy, and my experience is that a particular action is followed by relief, then I achieve relief if I think that action has occurred.

This book is recommended. At one level it should help people with chronic pain to understand that they haven't necessarily gone crazy, and that there may be no simple remedy. For those of us who treat pain it is a necessary and enjoyable read.

TRIP database

Bandolier has long been a fan of the TRIP database, which allows a quick one-stop shop for searching in Cochrane, DARE, HTA, lots of guidelines and ***Bandolier***. It has moved. The new address is http://www.ceres.uwcm.ac.uk/.

This is a bright new site with some interesting stuff, and well worth a visit and bookmarking.

Bandolier Conference

Stroke: what to do second – optimising secondary prevention and follow-up care

This was the subject of a ***Bandolier*** conference in London in March, and we have been asked to revisit the topic again, but in Manchester. The date is Thursday December 16, and the venue is the Stopford Room, Refectory Building, University of Manchester, Oxford Road, Manchester. The cost to NHS or university folk is £100, and for the private sector £250. A small number of reduced price places will be available for students. Fax Eileen Neail on 01865 226978, or call on 01865 226132, and she will send registration forms.

Programme

9.30 Registration and coffee

10.10 *Session 1: Where are we now, where do we want to go?*

Cathy Sudlow: evidence from anti-thrombotics trials
Nick Hicks: perspectives from primary care
Tony Snell: the Primary Care Clinical Effectiveness programme (PRICCE) and the secondary care interface

11.40 *Session 2: Pharmacological interventions*

Charles Forbes: the clinician in a clinical trials setting, the second ESPS
Martin Duerden: view from the National Prescribing Centre

13.30 *Session 3: Resource implications*

Tom Dent: option appraisals
Ceri Phillips: economic appraisals
James Overall: cost assessment

14.40 *Session 4: Non-pharmaceutical interventions*

TBA: the contribution of rehabilitation
Eoin Rederhan: the role of the Stroke Association

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